K123524

510(k) Summary

Company Medtronic Neurosurgery
125 Cremona Drive
Goleta, CA 93117

FEB 13 2013

Contact Donovan May
Senior Regulatory Affairs Specialist
Telephone: (805) 571-8758
Fax: (805) 571-8480
Email: donovan.may@medtronic.com

Date Prepared November 14, 2012

Device Name Medtronic Strata® NSC Lumboperitoneal Valve and Shunt System

Common Name Central Nervous System Flow Control Shunts and Accessories

Classification Name
Central Nervous System Fluid Shunt and Components (21 CFR 882.5550, Product Code JXG)

Predicate Devices

- PS Medical Strata NSC Lumboperitoneal Valve and Shunt System (K091312)
- PS Medical CSF-Lumboperitoneal Shunt (K831396)

Device Description:

The Strata NSC Lumboperitoneal Valve and Shunt Systems are comprised of lumbar and peritoneal catheters, valves and accessories. The lumboperitoneal valve allows the physician to noninvasively adjust the pressure/flow performance level pre- and post-implantation using magnetic adjustment tools in order to address changing patient needs. The lumbar catheters are available in closed-tip and open-tip configurations and have length markers located at 5 cm intervals. A strain relief provides support to and lessens the potential of catheter kinking at the junction of the lumbar catheter to the valve and fixation tabs are provided to anchor catheters at the incisions.

Technological Characteristics: The Strata NSC Lumboperitoneal Valve and Shunt Systems incorporate the same technological characteristics as that of the predicate devices and are identical to the currently marketed versions. Each of these devices is intended for draining of cerebral spinal fluid (CSF) from the lumbar subarachnoid space.

Indications for Use:

The Strata NSC Lumboperitoneal Shunt System provides continued cerebrospinal fluid (CSF) flow from the subarachnoid space into the peritoneal cavity. The Strata NSC Lumboperitoneal Valve allows the physician to non-invasively adjust the pressure/flow performance level pre- and post-implantation in order to address changing patient needs. The Strata NSC Lumboperitoneal Shunt System is designed for management of communicating hydrocephalus and may be used in the treatment of idiopathic intracranial hypertension (pseudotumor cerebri) when shunting is an option.

The Indications for Use statements cleared in the predicate submission K091312 did not contain language specific to the use of the subject devices for treatment of idiopathic intracranial hypertension (pseudotumor cerebri). The intent of this premarket submission is to expand the indications to include reference to this specific use when warranted.

Performance Data: Performance data demonstrating that the Strata NSC LP valves can be read and adjusted and that they do not migrate when properly implanted in an ovine model is included in this submission to support the indications expansion. Additionally a retrospective clinical review of data which includes prospective follow ups is provided to demonstrate that physicians are able to palpate the valve, determine the direction of flow and to accurately read the pressure level setting using the StrataVarius device consistently with radiographic imaging verification when these shunt systems are used for lumboperitoneal applications.

Conclusion: The Strata NSC Lumboperitoneal Valve and Shunt Systems are as safe and effective for the intended use of draining cerebrospinal fluid for the treatment of idiopathic intracranial hypertension (pseudotumor cerebri) as they are for other procedures for this intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2013

Medtronic Neurosurgery
c/o Donovan May
Senior Regulatory Affairs Specialist
125 Cremona Drive
Goleta, CA 93117

Re: K123524
Trade/Device Name: Medtronic Strata NSC Lumboperitoneal Valve and Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Shunt, Central Nervous System and Components
Regulatory Class: Class II
Product Code: JXG
Dated: November 14, 2012
Received: November 15, 2012

Dear Mr. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number: K123524

Device Name: Strata® NSC Lumboperitoneal Valve and Shunt System

Indications For Use:

The Strata NSC Lumboperitoneal Shunt System provides continued cerebrospinal fluid (CSF) flow from the subarachnoid space into the peritoneal cavity. The Strata NSC Lumboperitoneal Valve allows the physician to non-invasively adjust the pressure/flow performance level pre- and post-implantation in order to address changing patient needs. The Strata NSC Lumboperitoneal Shunt System is designed for management of communicating hydrocephalus and may be used in the treatment of idiopathic intracranial hypertension (pseudotumor cerebri) when shunting is an option.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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